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CONCEPTUAL MODEL FOR THE DIGITAL TRANSFORMATION OF MEDICAL RECORDS IN CHILE: A STANDARDIZED APPROACH ACCORDING TO FDA REGULATIONS

Modelo Conceptual para la Transformación Digital de Historias Clínicas en Chile: Un enfoque estandarizado de acuerdo con las regulaciones de la FDA

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ABSTRACT

This study addresses the management of medical information in Chile from the perspective of digital transformation. The objective of this study is to propose a standardized conceptual model for the digital transformation of medical records according to the FDA framework to reduce operating times and add value to clinical research in Chile. A semi-structured qualitative methodology was employed; insights from 39 health professionals, including researchers and industry members, were gathered through convenience sampling. Findings suggest that the digital transformation process can be standardized using a conceptual map, which would reduce data loss and operational inefficiencies while fostering the development of new research projects. The study concludes that implementing standardized electronic medical records in compliance with FDA guidelines is feasible and could significantly enhance the quality of medical care, support clinical research, and attract pharmaceutical investments.

Keywords: ACROCHI; electronic records; FDA standards; process standardization; sensitive data management.

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RESUMEN
Este estudio aborda el tratamiento de información médica en Chile desde la idea de transformación digital. El objetivo es proponer un modelo conceptual estandarizado de transformación digital de los registros médicos según el marco de la FDA, para reducir los tiempos operativos y agregar valor a la investigación clínica en Chile. Se empleó una metodología cualitativa semiestructurada, recopilando perspectivas de 39 profesionales de la salud, incluyendo investigadores y miembros de la industria mediante un muestreo por conveniencia. Los hallazgos sugieren que el proceso de transformación digital puede ser estandarizado utilizando un mapa conceptual, lo que reduciría la pérdida de datos y las ineficiencias operativas, al tiempo que fomentaría el desarrollo de nuevos proyectos de investigación. El estudio concluye que la implementación de registros médicos electrónicos estandarizados en cumplimiento con las directrices de la FDA es factible y podría mejorar significativamente la calidad de la atención médica, apoyar la investigación clínica y atraer inversiones farmacéuticas.

Palabras clave: ACROCHI; estándares FDA; estandarización de procesos; gestión de datos sensibles; registros electrónicos.

1. INTRODUCTION

The rapid evolution of pharmaceutical research, especially in response to crises like the COVID-19 pandemic, has highlighted the critical need for robust digital transformation in healthcare systems, with a particular emphasis on clinical studies. The development of new drugs, a fundamental aspect of pharmaceutical progress, is heavily regulated to ensure the safety and efficacy of treatments. Traditionally, these processes have relied on physical monitoring and data verification; research is often conducted by contractor research organizations or directly by pharmaceutical companies. However, the disruptions caused by the COVID-19 pandemic required the urgent adoption of digital systems to continue research without compromising participant safety, thus highlighting the importance of electronic medical records (EMR) and other digital tools to keep regulatory compliance and data integrity [1, 2].

The introduction of the FDA's Part 11 regulations in 1997 marked a significant advancement in the management of EMR [16, 17]. They established rigorous criteria for the validation and use of electronic records and signatures, aimed at ensuring that such systems are secure, reliable, and capable of preserving data integrity over extended periods [3, 4]. As digital transformation accelerates within the healthcare sector, compliance with Part 11 has become increasingly crucial, particularly in clinical research, because the integrity of data from clinical trials directly influences decisions regarding the quality, safety, and efficacy of new medical treatments. The ongoing global expansion of information and communication technologies in healthcare has further underscored the necessity of comprehensive e-health policies and optimized systems within healthcare centers to ensure that digital health initiatives are both effective and sustainable [5, 6].

Chile, like many other countries, faces significant challenges in adopting digital health technologies, particularly within clinical research. Despite the clear potential of digital transformation to enhance the efficiency and effectiveness of clinical studies, the country has been slow to embrace these changes, largely due to a reluctance to shift from traditional business models to more digitally oriented approaches. This resistance has prevented the development of the necessary clinical research infrastructure, which is particularly concerning given the essential role that clinical studies play in developing new treatments and drugs, especially in global health emergencies like the COVID-19 pandemic. The current digital infrastructure in Chilean medical centers is insufficient to meet the demands of modern clinical research, which heavily relies on the integration of electronic records and digital data management systems.

Considering these challenges, we pose this research question: What are the critical variables of medical records that can be represented by a conceptual model of digital transformation? Understanding these variables is essential for developing a robust framework that can guide the digital transformation of medical records within healthcare systems. Such a model would not only facilitate compliance with regulatory standards but also ensure that healthcare systems are equipped to meet the challenges of the future. The successful digital transformation of medical records is a complex, multidimensional process that requires the alignment of technological, regulatory, and organizational factors. By identifying and addressing the critical variables that influence this process, healthcare systems can be better prepared to leverage the full potential of digital technologies in improving patient care and advancing medical research.

With this in mind, the objective of this work is to propose a novel conceptual model for the digital transformation of medical records in both public and private sectors, standardized under the FDA's Part 11 of the Code of Federal Regulations. By aligning with these stringent regulations, the model aims to ensure data integrity and compliance, thereby supporting Chilean law 20584 and optimizing resources in clinical research. The contribution of this work lies in its potential to significantly reduce operating times and enhance the reliability of clinical studies, particularly in a rapidly evolving digital landscape, thereby adding substantial value to ongoing and future research efforts in the country.

2. METHODOLOGY

The study adopts a qualitative research paradigm through semi-structured interviews as the primary data collection method to explore the perceptions of key stakeholders in medical centers regarding the integration of FDA Part 11 compliance into medical records [7, 8]. This approach is systematic and aims at co-constructing a model that addresses regulatory requirements in clinical research.

The 39 participants were strategically selected through convenience sampling and comprised health professionals from both public and private sectors, including those with and without experience in clinical research, as well as professionals from pharmaceutical companies. The study population included members from the ACROCHI in Chile, the Chamber of Pharmaceutical Innovation, and various medical centers. The diverse professional backgrounds and significant experience levels of the participants provided a comprehensive perspective on the challenges and opportunities related to digital transformation in clinical research settings. Ethical considerations were meticulously observed throughout the study; all participants provided informed consent and were assured of confidentiality and the voluntary nature of their participation [9].

Semi-structured interviews were based on a set of 10 questions, divided into three separate stages, which were asked to all participants. The questions were validated by experts in the field, and feedback was received. The opinions of these professionals are considered an effective method for adjusting the instrument because they have experience in the subject, are recognized by others as qualified experts and can provide information, evidence, judgments, and assessments [10]. Subsequently, a pilot was conducted with three health professionals to adjust it to the reality of the environment and facilitate the achievement of the objective. The interviews were conducted online via video calls and were recorded. Each interview lasted approximately 45 minutes.

To analyze the collected data, key categories were defined based on the responses to the interviews. The analysis focused on identifying factors perceived by the participants as influencing the performance of their units, as well as gaps and opportunities for improvement. This methodological approach ensured

that data were interpreted within the context of each participant's experience and allowed us to identify critical variables that could inform the development of a conceptual model for digital transformation.

3. RESULTS

The analysis of the responses to each interview is presented below. For reasons of space and clarity in reading, only the information relevant to this article is included.

Stage 1: Approximately 54% of participants acknowledged the importance of digitalization, especially for managing chronic and long-standing patients. Participants' comments indicated, however, that the adoption and implementation of EMR in Chilean medical institutions are marked by significant variability and challenges. The effectiveness of EMR systems varied significantly across institutions, some use modules that only partially fulfilled their needs. As one participant noted, "*no software complied with the requirements of FDA regulation. It is more than an electronic record; it is a system that complements the procedures that are performed*" (E5). A notable portion of institutions still relied on mixed records (31%) or even paper records (15%), highlighting the ongoing difficulties in achieving full digital integration. Issues such as system failures and the inefficiency of existing electronic systems were significant barriers, as illustrated by one respondent who stated, "*The hospital's electronic record was not in line with the National Health Fund (FONASA in Spanish). It is a slow system with many steps and therefore generates resistance*" (E10).

Regarding the broader concept of digital transformation, the participants expressed mixed views. About 46% saw it as an essential, irreversible shift away from paper records, and emphasized the need for complete digitalization across all aspects of healthcare, from laboratories to pharmacies. Despite this, there was significant skepticism and concern, particularly regarding the trustworthiness and traceability of electronic systems, with some ethics committees being notably hesitant: "*Ethics committees are reluctant... They do not trust them and consider them hardly traceable. They are afraid of fraud in clinical research*" (E18). Another group (31%) viewed digital transformation as a potential avenue for enhancing professional communication and collaboration, though this optimism was tempered by recognition of the significant infrastructural and organizational challenges that must be overcome.

The actual use of medical records in practice reflected the complexities and limitations of the current digital systems. For 46% of the respondents, the transition to electronic records was fraught with challenges, including technical difficulties and the perception that digital systems added to the workload without improving patient care. One participant highlighted this sentiment by saying, "*I am left with the feeling of completing an administrative task rather than a clinical one*" (E25). Additionally, the implementation of digital systems often required substantial international support and long adaptation periods, underscoring the slow and difficult nature of this transformation. Some respondents highlighted the progressive nature of the digital transition, noting that this process could take years to fully integrate: "*It was a long process that took between 8 and 10 years... but the accreditation by the Ministry of Health accelerated this process*" (E35). These findings indicate that while digital transformation is recognized as necessary, its implementation is hindered by technical, organizational, and cultural barriers that must be addressed to realize its full potential.

Stage 2: The research identified several critical factors and proposals for successfully implementing digital transformation in medical records within Chilean healthcare facilities. One significant challenge stood out: the resistance among users, particularly older generations and medical professionals used to traditional methods. As one respondent noted, "*It is complex to change habits in older generations*"

(E18). Moreover, concerns about data management and security were prevalent, one participant expressed fear of "*interference by health insurance companies to the detriment of the patient*" (E23). This underscores the need for comprehensive user training and a cultural shift towards embracing digital tools in healthcare settings. Additionally, a lack of planning and resources was identified as a major obstacle, with respondents pointing out deficiencies in the implementation process, such as insufficient infrastructure and inadequate feedback mechanisms during the trial phases.

Despite these challenges, the study also uncovered significant opportunities to improve the use of electronic medical records. Most of the participants (62%) saw the potential for EMR to reduce errors, improve access to patient data, and decrease the time physicians spend on administrative tasks, thereby enhancing patient care. One participant remarked, "*With the electronic record, they finally understood the handwriting on the prescriptions*" (E34), highlighting a practical benefit of digitization. Furthermore, the pandemic was seen as a catalyst for change, with several respondents noting that "*COVID is the springboard to use to start talking about this*" (E9). This suggests that the current global health crisis could accelerate the adoption of digital records in Chilean healthcare institutions, thus providing a unique opportunity to modernize the system.

Participants also proposed high-impact strategies to facilitate this digital transformation. A significant proportion (46%) emphasized the importance of education at all levels, advocating for "*standardized training for people, with defined policies and clear process guidelines*" (E27). The design of the digital platforms themselves was also highlighted as crucial, with suggestions for creating interconnected systems that allow seamless access to patient records across different healthcare facilities. One participant stressed the need for a "*single platform design that would integrate all relevant systems, including public health funds and Family Health Centers, to streamline operations and reduce redundant medication dispensing*" (E27).

Incorporating FDA regulations into the digital transformation process was overwhelmingly supported by 77% of the interviewees, who believed that higher standards would enhance the credibility and safety of clinical research in Chile. As one participant noted, "*It is essential to have an electronic registry. Chile is small, and we must validate ourselves permanently*" (E10). The study's findings suggest that aligning with international standards could not only improve the quality of medical records but also position Chile more competitively in the global clinical research landscape. This support extends beyond clinical research, with participants recognizing the broader benefits of standardizing electronic records for overall patient care, potentially leading to a more efficient and reliable healthcare system.

Stage 3: The analysis identifies several critical factors for the successful implementation of digital transformation in healthcare institutions. A key facilitator, recognized by 54% of participants, is the support from management and government bodies. One participant highlighted that digital transformation results in "*a gain in time, decrease in human error and the possibility of conducting studies with larger populations*" (E11). However, barriers such as a "*less avant-garde work culture and less integration*" were also noted as significant challenges (E23).

Resource availability was another major factor, with 31% of interviewees emphasizing the need for adequate human and physical resources. The pandemic demonstrated the need for digital solutions to the issue of resources, as one respondent noted, "*The pandemic forced people to learn to use telemedicine, which had already been available for more than 19 years*" (E16). External financial support was also deemed crucial due to the associated costs.

Communication emerged as a significant hindrance, with 31% stressing the importance of involving all stakeholders in decision-making. One respondent criticized the exclusionary approach, stating, "*[The decision-makers] did not include the personnel who use the record... They should carry out a survey, inform*

about the change, and generate discussion" (E12). Participants recommended thorough planning, effective communication, and a progressive implementation approach with "*continuous training and ongoing support*" to ensure success (E17).

3.1. Conceptual model

The study successfully achieved its objective by identifying key context analysis components and proposing an interaction model for digital transformation (Figure 1). The research outlined a systematic approach, beginning with the knowledge stage, where current practices and technological gaps should be assessed against FDA requirements.

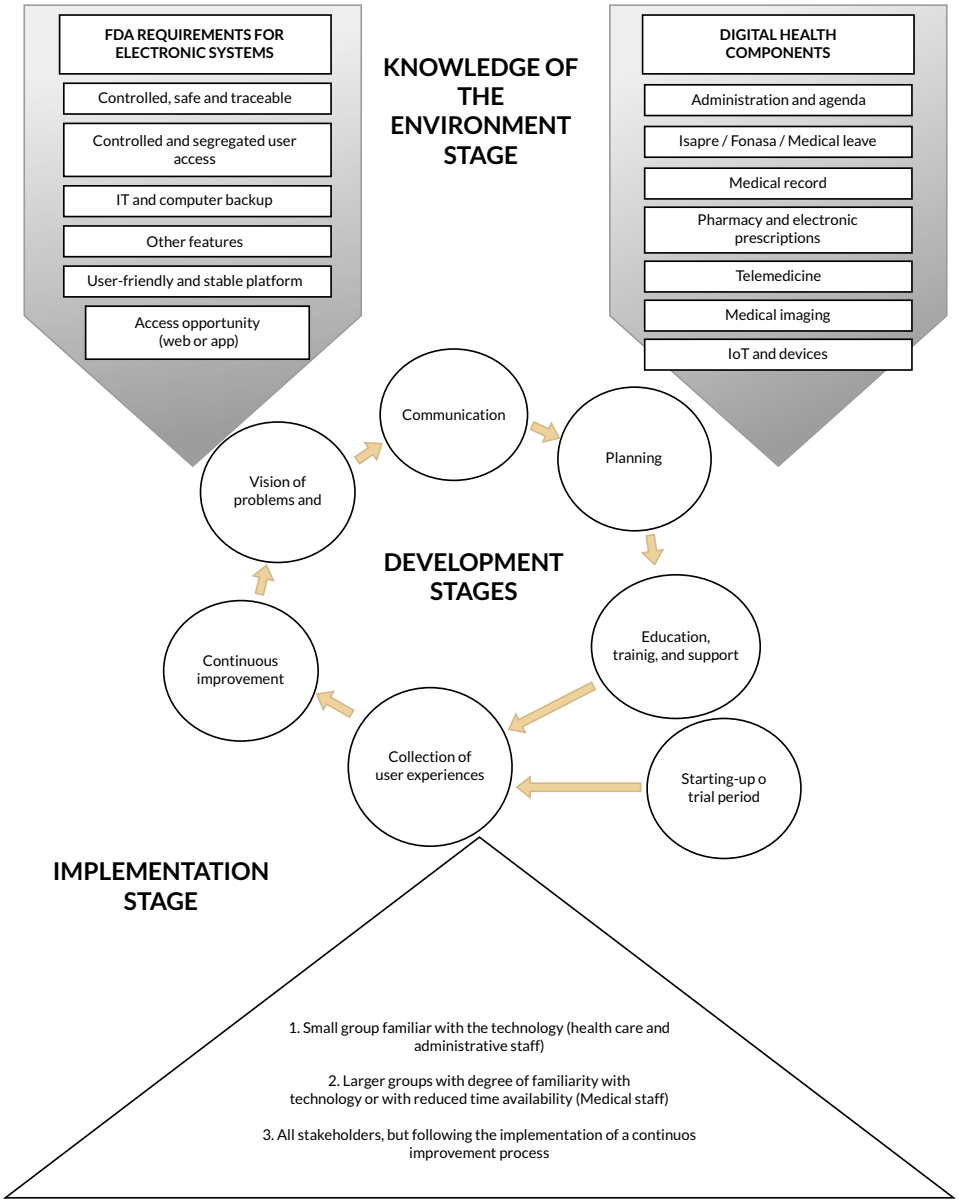

Figure 1. *Conceptual model for the digital transformation of electronic medical records (Source: Authors)*

The knowledge stage should be followed by the development stage, emphasizing comprehensive planning, user training, and continuous feedback to ensure seamless integration of electronic medical records. Finally, the implementation stage should involve a phased approach, tailored to user familiarity with technology and the operational demands of different hospital units. This structured methodology ensures that the digital transformation aligns with both regulatory standards and user needs, promoting a successful transition to electronic systems in healthcare.

4. DISCUSSION AND CONCLUSIONS

This research identifies a fragmented approach to digital transformation in Chilean healthcare, where 54% of institutions have independently implemented systems like electronic records and inventory management. However, these systems are not integrated, either within or across institutions, highlighting a significant disconnect from the broader digital health strategy envisioned by SIDRA [11, 12]. This fragmentation underlines the urgent need for a cohesive national strategy that prioritizes interoperability and aligns with a unified vision for digital transformation.

The study also reveals substantial challenges in user adoption, driven by a lack of awareness about the benefits of digital systems and generational disparities in technology use. To address these barriers, the proposed conceptual model incorporates elements from digital transformation maturity models, ensuring that the digital implementation resonates with institutional culture and employee readiness. The model advocates a user-centered approach, focusing on education, training, and the development of soft skills necessary for successful digital integration [13, 14].

Furthermore, the research emphasizes the critical role of regulatory frameworks and stakeholder engagement. Aligning electronic records with FDA guidelines will ensure compliance and enhance data security, essential for clinical research and broader healthcare applications [15]. The study concludes that a structured, phased implementation supported by continuous feedback and strategic communication is vital for successful digital transformation in healthcare.

The security of personal clinical data is paramount in the implementation of platforms handling highly confidential information, particularly in electronic health record systems. Privacy and security must be rigorously addressed to ensure patient trust and prevent breaches of medical data confidentiality. The critical nature of medical information requires robust security measures to prevent unauthorized access, ensuring that only authorized individuals can handle the data. This is vital for maintaining trust, especially during global health emergencies and the development of new therapies and treatments [18, 19].

In conclusion, the study asserts that successful digital transformation of medical records depends on understanding the environment, clear vision, strategic planning, and phased implementation. The proposed model standardizes these elements, facilitating better interaction among healthcare professionals and improving record usability for both operational and research purposes. Future actions should include revising digital transformation plans, integrating IT systems, and educating managers, alongside creating a compliant platform that adheres to regulatory standards and fosters multisectoral strategies at the state level.

AUTHORS' CONTRIBUTIONS

Carla Rodríguez Vergara: Conceptualization; Methodology; Formal analysis; Investigation; Writing-original draft and editing. **Héctor Valdés-González**: Conceptualization; Data curation; Formal analysis; Investigation; Visualization; Writing-original draft. **Lorenzo Reyes-Bozo**: Conceptualization; Methodology; Formal analysis; Investigation; Writing-review and editing. **Juan Carlos Vidal**: Investigation; Visualization; Writing-review and editing.

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